Remarks

The Specification of the above-captioned application has been amended to correct an inadvertent typographical error.

Claim 31 has been amended. New claims 32-34 have been added. Support for the amendments to claim 31 and new claims 32-34 can be found in general throughout Applicants' Specification and in particular, for example, as follows: claim 31, page 5, lines 16-18, claims 32-34, page 8, lines 4-7. No new matter has been added.

I. Rejections under 35 U.S.C. §103

A. Claims 1, 3, 4, 8, 10, 13, 15, 18, and 31 stand rejected under 35 U.S.C. § 102(b) over Brennan (AU 200157788) with Hynes et al. (U.S. 2002/0192350).

Brennan discloses a method of manufacturing effervescent tablets in which the tablets can be manufactured in a normal or ambient environment to allegedly produce tablets that are less affected by atmospheric humidity (Brennan, page 2, lines 4-7). Brennan further discloses including cranberry extract, glucosamine or ubidecarenone in his tablets (*Id.*, lines 14-16).

Claim 1 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent including an acid and a base, binder, and lubricant, the tablet disintegrating in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. The tablet of Brennan does not disintegrate in water having a temperature of about 22°C in less than 2.5 minutes (see Declaration of Kyle M. Johnson, which is attached hereto at Exhibit A). Therefore Brennan cannot anticipate the tablet of claim 1.

It is undisputed that Hynes et al. do not teach an effervescent tablet that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 102(b) over Brennan with Hynes et al. has been overcome and respectfully requests that it be withdrawn.

Claims 3, 4, 8, 10, 13, 15, 18, and 31 are distinguishable under 35 U.S.C. § 102(b) over Brennan and Hynes et al. for at least the same reasons set forth above in distinguishing claim 1.

Claims 1, 5-9, and 31 stand rejected under 35 U.S.C. § 103 over Brennan in view of Mann (U.S. 6,231,866) (hereinafter "Mann").

The discussion of Brennan set forth above is incorporated herein.

Mann discloses a dietary supplement produced by infusing plant-derived fiber with juice concentrate and drying the fiber (Mann, col. 3, lines 49-52). Mann refers to "plant-derived fiber" as "pomace" throughout his application (see, *Id.*, ll. 52-55). Mann also describes a tablet that includes cranberry pomace. According to Mann, the fiber portion of his product (i.e., the pomace) is insoluble (*Id.*, col. 5, ll. 50-51). Mann discloses that CRAN-MAX is produced by infusing cranberry juice concentrate into cranberry pomace (*Id.*, col. 6, ll. 27-29). Mann further discloses that CRAN-MAX can be taken in pill or capsule form to "afford an individual the known benefits of cranberry without ingesting unwanted additives such as sweeteners and colorants" (*Id.*, ll. 34-38).

Claim 1 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent including an acid and a base, binder, and lubricant, the tablet disintegrating in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. As established above, the tablet of Brennan does not disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Therefore the tablet of Brennan does not anticipate the tablet of claim 1. Brennan also does not teach or suggest how to formulate his effervescent tablet such that it disintegrates in water having a temperature of about 22°C in less than 2.5 minutes.

Mann does not cure the deficiencies of Brennan. Mann does not teach or suggest a tablet that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. Mann also does not teach or suggest how to formulate an effervescent tablet such that it disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. Therefore, the proposed combination of Brennan and Mann lacks a required element of claim 1 and also fails to enable the skilled artisan to achieve the tablet of

claim 1. The rejection of claim 1 under 35 U.S.C. § 103 over Brennan in view of Mann thus has been overcome, and Applicants respectfully requests that it be withdrawn.

Claims 5-9 and 31 are distinguishable under 35 U.S.C. § 103 over Brennan in view of Mann for at least the same reasons set forth above in distinguishing claim 1. Claims 5-7 and 9 are further distinguishable for at least the following additional reasons.

Claim 5

Claim 5 depends from claim 1 and further specifies that the tablet includes at least 500 mg cranberry extract. Brennan does not teach or suggest including at least 500 mg cranberry extract in an effervescent tablet. Brennan also does not teach or suggest how to formulate an effervescent tablet to include at least 500 mg cranberry extract and to disintegrate in water having a temperature of about 22°C in less than 2.5 minutes.

Mann does not cure the deficiencies of Brennan. Mann does not teach or suggest a tablet that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. Mann also does not teach or suggest how to form an effervescent tablet so as to include at least 500 mg cranberry extract and to disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Therefore, the proposed combination of Brennan and Mann lacks a required element of claim 5 and further fails to enable the skilled artisan to achieve the tablet of claim 5.

The rejection of claim 5 is further deficient in that Mann discloses that his CRAN-MAX is infused in pomace, which he discloses as being an insoluble fiber portion (*Id.*, col. 5, ll. 50-51 and col. 6, ll. 27-29). Brennan discloses, "Effervescent tablets differ from normal tablets in that they are designed to be dissolved in a glass of cool water before the resulting solution is swallowed" (Brennan, page 2, ll. 20-21). Mann does not teach or suggest that the CRAN-MAX will dissolve in water. Therefore, the skilled artisan would not think to include CRAN-MAX in the effervescent composition of Brennan and further would have no reason to include at least 500 mg of CRAN-MAX in the composition of Brennan. For at least these additional reasons Applicants submit that the rejection of claim 5 under 35 U.S.C. § 103 over Brennan in view of Mann has been overcome and respectfully requests that it be withdrawn.

Claim 6

Claim 6 depends from claim 1 and further specifies that the tablet includes from about 750 mg to about 1500 mg cranberry extract. Brennan does not teach or suggest including from about 750 mg to about 1500 mg cranberry extract in an effervescent tablet. Brennan also does not teach or suggest how to formulate an effervescent tablet to include from about 750 mg to about 1500 mg cranberry extract and to disintegrate in water having a temperature of about 22°C in less than 2.5 minutes.

Mann does not cure the deficiencies of Brennan. Mann does not teach or suggest how to form an effervescent tablet so as to include from about 750 mg to about 1500 mg cranberry extract and to disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Therefore, the proposed combination of Brennan and Mann fails to enable the skilled artisan to achieve the tablet of claim 6. Applicants submit, therefore, that the rejection of claim 6 under 35 U.S.C. § 103 over Brennan in view of Mann has been overcome and respectfully requests that it be withdrawn.

The rejection of claim 6 is further deficient in that Mann discloses that his CRAN-MAX is infused in pomace, which he discloses as being an insoluble fiber portion (*Id.*, col. 5, ll. 50-51 and col. 6, ll. 27-29). Brennan discloses, "Effervescent tablets differ from normal tablets in that they are designed to be dissolved in a glass of cool water before the resulting solution is swallowed" (Brennan, page 2, ll. 20-21). Mann does not teach or suggest that the CRAN-MAX will dissolve in water. Therefore, the skilled artisan would not think to include CRAN-MAX in the effervescent composition of Brennan and further would have no reason to include from about 750 mg to about 1500 mg of CRAN-MAX in the composition of Brennan. For at least these additional reasons Applicants submit that the rejection of claim 6 under 35 U.S.C. § 103 over Brennan in view of Mann has been overcome and respectfully requests that it be withdrawn.

Claim 7

Claim 7 depends from claim 1 and further specifies that the tablet includes about 1000 mg cranberry extract. Claim 7 depends from claim 1 and further specifies that the tablet includes about 1000 mg cranberry extract. Brennan does not teach or suggest including about 1000 mg cranberry extract in an effervescent tablet. Brennan also does not teach or suggest how to formulate an effervescent tablet to include about 1000 mg

cranberry extract and to disintegrate in water having a temperature of about 22°C in less than 2.5 minutes.

Mann does not cure the deficiencies of Brennan. Mann does not teach or suggest how to form an effervescent tablet so as to include about 1000 mg cranberry extract and to disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Therefore, the proposed combination of Brennan and Mann fails to enable the skilled artisan to achieve the tablet of claim 7. Applicants submit, therefore, that the rejection of claim 7 under 35 U.S.C. § 103 over Brennan in view of Mann has been overcome and respectfully requests that it be withdrawn.

The rejection of claim 7 is further deficient in that Mann discloses that his CRAN-MAX is infused in pomace, which he discloses as being an insoluble fiber portion (*Id.*, col. 5, ll. 50-51 and col. 6, ll. 27-29). Brennan discloses, "Effervescent tablets differ from normal tablets in that they are designed to be dissolved in a glass of cool water before the resulting solution is swallowed" (Brennan, page 2, ll. 20-21). Mann does not teach or suggest that the CRAN-MAX will dissolve in water. Therefore, the skilled artisan would not think to include CRAN-MAX in the effervescent composition of Brennan and further would have no reason to include about 1000 mg of CRAN-MAX in the composition of Brennan. For at least these additional reasons Applicants submit that the rejection of claim 7 under 35 U.S.C. § 103 over Brennan in view of Mann has been overcome and respectfully requests that it be withdrawn.

Claim 9

Claim 9 depends from claim 1 and further specifies that the tablet includes from 10 % by weight to 35 % by weight cranberry extract. Brennan does not teach or suggest including from 10 % by weight to 35 % by weight cranberry extract in an effervescent tablet. Brennan also does not teach or suggest how to formulate an effervescent tablet to include from 10 % by weight to 35 % by weight cranberry extract and to disintegrate in water having a temperature of about 22°C in less than 2.5 minutes.

Mann does not cure the deficiencies of Brennan. Mann does not teach or suggest including from 10 % by weight to 35 % by weight cranberry extract in an effervescent composition. Mann also does not teach or suggest how to form an effervescent tablet so as to include from 10 % by weight to 35 % by weight cranberry extract and to

disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Therefore, the proposed combination of Brennan and Mann fails to enable the skilled artisan to achieve the tablet of claim 9. Applicants submit, therefore, that the rejection of claim 9 under 35 U.S.C. § 103 over Brennan in view of Mann has been overcome and respectfully requests that it be withdrawn.

B. Claims 1, 11, and 12 stand rejected under 35 U.S.C. § 103 over Brennan in view of Higuchi et al. (U.S. 3,764,668).

The discussion of Brennan set forth above is incorporated herein.

Higuchi et al. describe an orally administered pharmaceutical composition that includes an alkali metal salt of salicylamide (Higuchi et al., Abstract). Higuchi et al. list a variety of optional ingredients that can be included in his pharmaceutical composition of alkali metal salts of salicylamide. Included in this list are diluents, binders, lubricants, disintegrators, and coloring agents (*Id.*, col. 4, ll. 45-48). Higuchi et al. disclose that typical diluents include dicalcium phosphate, calcium sulfate, lactose, kaolin, mannitol, sorbitol, dry starch, and powdered sugar (*Id.*, ll. 54-55). Higuchi et al. further disclose that typical binders include starch, gelatin, sugars such as sucrose, molasses and lactose, natural and synthetic gums such as acacia, sodium alginate, extract of Irish moss, carboxymethyl cellulose, methylcellulose, polyvinylpyrrolidone, polyethylene glycol, ethylcellulose, and waxes. (*Id.*, ll. 56-61).

Claim 1 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent including an acid and a base, binder, and lubricant, the tablet disintegrating in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. As established above, the tablet of Brennan does not disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Therefore the tablet of Brennan does not anticipate the tablet of claim 1. Brennan also does not teach or suggest how to formulate his effervescent tablet such that it disintegrates in water having a temperature of about 22°C in less than 2.5 minutes.

Higuchi et al. do not cure the deficiencies of Brennan. Higuchi et al. do not teach or suggest a tablet that disintegrates in water having a temperature of about 22°C in less

than 2.5 minutes. Higuchi et al. also do not teach or suggest how to formulate an effervescent tablet such that it disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. To the contrary, the only discussion pertaining to disintegration rates present in Higuchi et al. is related to the dissolution of salicylamide and sodium salicylamide, which takes 20 minutes to completely dissolve. Therefore, the proposed combination of Brennan and Higuchi et al. fails to teach a required property of the tablet of claim 1 and further fails to enable the skilled artisan to achieve the tablet of claim 1. Accordingly, the rejection of claim 1 under 35 U.S.C. § 103 over Brennan in view of Higuchi et al. has been overcome, and Applicants' respectfully requests that it be withdrawn.

Claims 11 and 12 are distinguishable over the proposed combination of Brennan in view of Higuchi et al. for at least the same reasons set forth above in distinguishing claim 1.

Claim 12

Claim 12 is further distinguishable under 35 U.S.C. § 103 over Brennan in view of Higuchi et al. for at least the following additional reasons. Claim 12 depends from claim 1 and further specifies that the binder of the tablet includes from 20 % by weight to 25 % by weight sorbitol. Brennan does not teach or suggest including any sorbitol in his effervescent tablet –let alone from 20 % by weight to 25 % by weight sorbitol.

Higuchi et al. do not cure the deficiencies of Brennan. Higuchi et al. do not teach or suggest including sorbitol in a tablet that includes cranberry extract --let alone including from 20 % by weight to 25 % by weight sorbitol in such a composition. Higuchi et al. disclose that their optional ingredients can be included in an amount that ranges between about 0.01 % by weight and 20 % by weight. A range of between about 0.01 % by weight and 20 % by weight does not include the end point 20 % by weight. Therefore the proposed combination of Brennan and Higuchi et al. fails to teach a required element of claim 12. For this reason alone, the rejection of claim 12 under 35 U.S.C. § 103 over Brennan in view of Higuchi et al. cannot stand and must be withdrawn.

The proposed combination is further deficient for at least the following additional reasons. Higuchi et al. also do not teach or suggest including sorbitol as a binder in an effervescent composition. To the contrary, Higuchi et al. disclose that sorbitol is a

diluent. Brennan does not teach or suggest including diluent in his effervescent composition. Therefore, the skilled artisan would have no reason to include the sorbitol diluent of Higuchi et al. in the composition of Brennan. Moreover, nothing in Higuchi et al. teaches or suggests that a tablet that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes and could be successfully formed using sorbitol as the binder or by including from 20 % by weight to 25 % by weight sorbitol. Furthermore to attempt to arrive at the composition of claim 12, the skilled artisan would have to make a series of selections for which there is no particular direction. First the skilled artisan would have to decide to select a diluent from the list of many optional ingredients disclosed by Higuchi et al. for inclusion in the Brennan composition even though Brennan does not teach or suggest including diluent in his composition. Then the skilled artisan would have to select sorbitol from the list of more than eight diluents when nothing in Higuchi et al. directs the skilled artisan to make this specific selection. Then, the skilled artisan would have to decide to include an amount of sorbitol that is outside of the range disclosed by Higuchi et al. when there is no teaching or suggestion to do so. In other words, claim 12 requires at least 20 % by weight sorbitol. Nothing in Higuchi et al. directs the skilled artisan to include an amount of diluent that is greater than the end point of their disclosed range or to go beyond their disclosed range with the diluent sorbitol in particular. Thus, the skilled artisan would have no reason to *sua sponte* do so. Moreover, nothing in Brennan teaches or suggests that a viable tablet could be made with from 20 % by weight to 25 % by weight sorbitol. Thus, the skilled artisan would have no reasonable expectation of successfully including such a large amount of diluent in the tablet of Brennan. Applicants submit, therefore, that the rejection of claim 12 under 35 U.S.C. § 103 over Brennan in view of Higuchi et al. has been overcome and respectfully requests that it be withdrawn.

C. Claims 1 and 14 stand rejected under 35 U.S.C. § 103 over Brennan in view of Mann (2002/0102336) (hereinafter "Mann II").

The discussion of Brennan set forth above is incorporated herein.

Mann II discloses a method of stabilizing fruit concentrate (Mann II, Abstract). The method includes blending the fruit with an aqueous solution that includes magnesium

hydroxide, an organic acid component, and a stabilizer, and drying the fruit to produce a dried fruit powder (*Id.*, para. [0007]).

Claim 1 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent including an acid and a base, binder, and lubricant, the tablet disintegrating in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. As established above, the tablet of Brennan does not disintegrate in water having a temperature of about 22°C in less than 2.5 minutes. Therefore the tablet of Brennan does not anticipate the tablet of claim 1. Brennan also does not teach or suggest how to formulate his effervescent tablet such that it disintegrates in water having a temperature of about 22°C in less than 2.5 minutes.

Mann II does not cure the deficiencies of Brennan. It is undisputed that Mann II does not teach or suggest a tablet that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes. Nothing in the record establishes anything to the contrary. Thus the proposed combination of Brennan and Mann II fails to teach or suggest a required property of the tablet of claim 1. The proposed combination also fails to enable the skilled artisan to achieve the tablet of claim 1. As such, the rejection of claim 1 under 35 U.S.C. § 103 over Brennan in view of Mann II cannot stand, and Applicants respectfully requests that it be withdrawn.

Claim 14 is distinguishable under 35 U.S.C. § 103 over Brennan in view of Mann II for at least the same reasons set forth above in distinguishing claim 1.

D. Claims 1, 2, 5-10, 13, 16, 18, and 31 stand rejected under 35 U.S.C. § 103 over Nawar (U.S. 6,641,847) in view of Lieberman et al. eds. (Mohrle, Raymond, "Effervescent Tablets," *Pharmaceutical Dosage Forms: Tablets*, Second Edition, volume 1, New York: Marcel Dekker, Inc., 1989, pp. 285-303), hereinafter referred to as "Mohrle."

Nawar discloses isolated cranberry seed oil and a method for extracting cranberry seed oil from cranberry seeds (Nawar, col. 2, ll. 27-35). Nawar also describes providing a therapeutic composition (e.g., a food stuff, dietary supplement, or pharmaceutical composition) that includes isolated cranberry seed oil or a compound derived from

cranberry seed oil such as a cranberry seed oil extract that is substantially free of impurities. Nawar explains that his extract can include flavonoid (e.g., isoflavone), fatty acids, a sterol or a tocopherol (*Id.*, col. 2, ll. 38-52). Nawar also discloses that his cranberry seed oil extracts can be formulated as a pharmaceutical composition, added to various foodstuffs, or used in cosmetics (*Id.*, col. 18, ll. 35-65).

Mohrle discusses effervescent tablet technology in general including formulation, manufacture and disintegration of effervescent tablets. Mohrle discloses, "[i]f the tablet components are not soluble, the effervescent reaction will not occur and the tablet will not disintegrate quickly" (Mohrle, page 287). Mohrle further discloses that "[t]he rate of solubility is perhaps even more important than solubility per se since a slowly dissolving soluble substance can hinder tablet disintegration and provide a slowly soluble, often objectionable residue after the tablet disintegrates" (*Id*). Mohrle also discloses that the use of a binder is limited because binders will retard the disintegration of an effervescent tablet (*Id.*, page 291). Mohrle then discloses,

> Many substances are effective lubricants in certain concentrations but inhibit tablet disintegration at these same concentrations. When the concentration is lowered to permit the tablet to properly disintegrate, the lubricating efficiency of the material is lost or so greatly diminished that it is no longer useful. If a clear solution is desired when the tablet disintegrates, the problem is even greater since the most efficient lubricants are water-insoluble and will leave a cloudy solution once dispersed.

(*Id.*, page 292).

Claim 1 is directed to an effervescent tablet that includes an effervescent composition including at least 200 mg cranberry extract, an effervescent agent that includes an acid and a base, binder, and lubricant, where the tablet disintegrates in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. It is undisputed that Nawar fails to teach or suggest including his cranberry seed oil in an effervescent composition. Nawar also does not teach or suggest forming his cranberry seed oil into a composition that disintegrates in water. Nawar further fails to describe utilizing his cranberry seed oil in conjunction with water. Nawar does not teach or suggest that his cranberry seed oil is water soluble or that it

could be formulated into a composition that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. Nawar discloses that his cranberry seed oil is extracted using non-polar organic solvents such as hexane –not water (see, Nawar, e.g., col. 20, ll. 40-46, Example 1, and col. 22, ll. 55-57). Therefore, the skilled artisan would have no reason to believe that the cranberry seed oil of Nawar could be formulated into a composition that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles.

Mohrle does not cure the deficiencies of Nawar. Mohrle indicates that effervescent granulations are inherently difficult to lubricate because many substances that are effective lubricants inhibit tablet disintegration (*Id.*, page 292). Mohrle further explains that for intrinsic lubrication, a concentration of 1 % or less of some water insoluble lubricants is usually effective, but because such lubricants are not water soluble they can hinder tablet disintegration and produce cloudy solutions (*Id.*). Indeed, although Mohrle generally discloses the use of oils as lubricants to facilitate the processing of effervescent compositions, Mohrle does not teach or suggest including at least 200 mg of lubricating oil in an effervescent composition. Mohrle also does not teach or suggest that it was known to include at least 200 mg of an oil in an effervescent tablet prior to the filing date of the above-captioned application. Moreover, Nawar describes using cranberry seed oil as an active agent in a therapeutic composition. Mohrle does not teach or suggest including active agents in the form of oils in effervescent compositions. Mohrle further fails to teach or suggest including at least 200 mg of an active agent in the form of an oil in an effervescent composition. Therefore, the skilled artisan would not think to do so.

Mohrle also provides no direction as to how to include at least 200 mg of an oil in an effervescent tablet --much less how to include such an amount of an oil and still obtain a tablet that disintegrates in less than 2.5 minutes. Therefore the person of skill in the art would have no clue as to how to formulate such a tablet and would have no reasonable expectation of successfully achieving a tablet that disintegrates in less than 2.5 minutes from the combined disclosures of Nawar and Mohrle. Accordingly, the rejection

of claim 1 under 35 U.S.C. § 103 over Nawar in view of Mohrle is unwarranted, and Applicants respectfully request that it be withdrawn.

Claims 2, 5–10, 13, 16, 18, and 31 are distinguishable under 35 U.S.C. § 103 over Nawar in view of Mohrle for at least the same reasons set forth above in distinguishing claim 1. Claims 5-7, 13, 16, and 31 are further distinguishable for at least the following additional reasons.

Claim 5

Claim 5, which depends from claim 1, is directed to an effervescent tablet that includes at least 500 mg cranberry extract. As indicated above with respect to claim 1, Nawar is specifically directed to a composition that includes cranberry seed oil. Nawar does not teach or suggest including at least 500 mg of his cranberry seed oil in a tablet, let alone an effervescent tablet.

Mohrle also does not teach or suggest including at least 500 mg cranberry seed oil or a cranberry extract in an effervescent tablet. Accordingly, Applicants submit that a *prima facie* case of obviousness of claim 5 has not been established. Mohrle is further deficient in that nothing in Mohrle teaches or suggests how to include at least 500 mg of the cranberry seed oil of Nawar in an effervescent tablet, much less how to include such an amount and still obtain a tablet that disintegrates in less than 2.5 minutes. Therefore, the person of skill in the art would not think to include at least 500 mg of the cranberry seed oil of Nawar in an effervescent tablet and further would have no clue as to how to do so and achieve a tablet that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. The skilled artisan also would have no reasonable expectation of successfully achieving such a tablet. Accordingly, Applicants submit that the rejection of claim 5 under 35 U.S.C. § 103 over Nawar in view of Mohrle cannot stand for at least these additional reasons.

Claim 6

Claim 6, which depends from claim 1, is directed to an effervescent tablet that includes at least 750 mg cranberry extract. As indicated above with respect to claim 1, Nawar is specifically directed to a composition that includes cranberry seed oil. Nawar does not teach or suggest formulating at least 750 mg of his cranberry seed oil in a tablet, let alone an effervescent tablet.

Mohrle also does not teach or suggest including at least 750 mg cranberry extract, or at least 750 mg of the cranberry seed oil in an effervescent tablet. Therefore, the proposed combination of Nawar and Mohrle fails to teach a required element of the tablet of claim 6. As such a *prima facie* case of obviousness of claim 6 has not been established. For this reason alone the rejection of claim 6 under 35 U.S.C. § 103 over Nawar in view of Mohrle cannot stand and must be withdrawn.

Mohrle is further deficient in that Mohrle also does not teach or suggest how to include at least 750 mg of the cranberry seed oil of Nawar in an effervescent tablet, much less how to include such an amount of cranberry seed oil and still obtain a tablet that disintegrates in less than 2.5 minutes. Therefore, the person of skill in the art would not think to formulate at least 750 mg of the cranberry seed oil of Nawar as an effervescent tablet and further would have no clue as to how to do so. Moreover, the skilled artisan would have no reasonable expectation of successfully achieving a tablet that includes such an amount of cranberry seed oil and disintegrates in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of granules and particles. Applicants submit, therefore, that the rejection of claim 6 under 35 U.S.C. § 103 over Nawar in view of Mohrle is further unwarranted for at least these additional reasons and request that it be withdrawn.

Claim 7

Claim 7, which depends from claim 1, is directed to an effervescent tablet that includes at least 1000 mg cranberry extract. As indicated above with respect to claim 1, Nawar does not teach or suggest formulating at least 1000 mg of cranberry extract as an effervescent tablet.

Nothing in Mohrle teaches or suggests including at least 1000 mg of cranberry extract in an effervescent tablet. Therefore, the proposed combination of Nawar and Mohrle fails to teach a required element of the tablet of claim 7. As such a *prima facie* case of obviousness of claim 7 has not been established. For this reason alone the rejection of claim 7 under 35 U.S.C. § 103 over Nawar in view of Mohrle cannot stand and must be withdrawn.

The proposed combination is further deficient for at least the following additional reasons. The record fails to enable the skilled artisan to make a tablet that includes at

least 1000 mg of the cranberry seed oil extract of Nawar in an effervescent tablet in general and in an effervescent tablet that disintegrates in less than 2.5 minutes in particular. The record also fails to establish a reason why the skilled artisan would *sua sponte* decide to include at least 1000 mg of cranberry extract in an effervescent tablet. The only possible way to attempt arrive at the tablet of claim 7 through the proposed combination of Nawar and Mohrle would be through hindsight reconstruction, which is impermissble. Accordingly, Applicants submit that the rejection of claim 7 under 35 U.S.C. § 103 over Nawar in view of Mohrle is unwarranted and cannot stand.

Claim 13

Claim 13 depends from claim 1 and specifies that the effervescent tablet disintegrates in water having a temperature of about 22°C in less than 2.5 minutes to form a solution that is free of surface scum. It is undisputed that Nawar does not teach or suggest an effervescent composition. Nawar also does not teach or suggest a composition that disintegrates in water to form a solution that is free of surface scum. The only cranberry extract Nawar discloses is a cranberry seed oil extract. Nawar does not teach or suggest that his cranberry seed oil is water soluble or that it would form a solution that is free of surface scum.

This deficiency of Nawar is not cured by Mohrle. Mohrle does not teach or suggest incorporating a cranberry seed oil such as the one described in Nawar in an effervescent tablet. Mohrle also does not teach or suggest incorporating at least 200 mg of such a cranberry seed oil in an effervescent tablet. Mohrle discloses that when "tablet components are not soluble, the effervescent reaction will not occur and the tablet will not disintegrate quickly" (Mohrle, page 287). Mohrle further discloses,

> Many substances are effective lubricants in certain concentrations but inhibit tablet disintegration at these same concentrations. When the concentration is lowered to permit the tablet to properly disintegrate, the lubricating efficiency of the material is lost or so greatly diminished that it is no longer useful. If a clear solution is desired when the tablet disintegrates, the problem is even greater since the most efficient lubricants are water-insoluble and will leave a cloudy solution once dispersed.

(*Id.*, page 292). Applicants' Specification demonstrates an example in which cranberry oil extract was present in an effervescent composition. When the composition was placed in water, a layer of oil formed on top of the water. Mohrle does not teach or suggest how to incorporate at least 200 mg of the cranberry seed oil of Nawar in an effervescent tablet that disintegrates in water to produce a solution that is free of surface scum. Therefore the person of skill in the art would have no idea how to formulate the cranberry seed oil of Nawar into an effervescent tablet that disintegrates into a solution free of surface scum, and further would have no reasonable expectation of successfully achieving such a tablet. For at least these additional reasons, Applicants submit that the rejection of claim 13 under 35 U.S.C. § 103 over Nawar in view of Mohrle is unwarranted and respectfully request that it be withdrawn.

Claim 16

Claim 16 is directed to a tablet that includes an effervescent composition that includes from 50 mg to 200 mg cranberry seed oil, and an effervescent agent that includes an acid and a base, the tablet having a hardness of at least 5 kilopounds and disintegrating in water less than 2.5 minutes. Nawar discloses cranberry seed oil. It is undisputed that Nawar fails to teach or suggest including his cranberry seed oil in an effervescent composition. Nawar also does not teach or suggest forming his cranberry seed oil into a composition that disintegrates in water.

Mohrle does not cure the deficiencies of Nawar. Mohrle does not teach or suggest including from 50 mg to 200 mg oil –let alone cranberry seed oil-- in an effervescent tablet. Mohrle also does not suggest that such an amount of cranberry seed oil can be included in an effervescent tablet. To the contrary, although Mohrle indicates that oils have been used as lubricants in effervescent compositions, Mohrle discloses that effervescent granulations are inherently difficult to lubricate because many substances that are effective lubricants inhibit tablet disintegration (*Id.*, page 292). Mohrle further explains that for intrinsic lubrication a concentration of 1 % or less of some water insoluble lubricants is usually effective, but because such lubricants are not water soluble they can hinder tablet disintegration and produce cloudy solutions (*Id.*). For an effervescent tablet to include from 50 mg to 200 mg of an oil lubricant, the effervescent tablet would have to weigh, at a minimum, from 5000 mg to 20,000 mg. Mohrle does not

teach or suggest effervescent tablets that weigh from 5000 mg to 20,000 mg and that include lubricating oil. Moreover, Nawar does not teach or suggest using his cranberry seed oil as a lubricant. Therefore, the skilled artisan would have no reason to include from 50 mg to 200 mg cranberry seed oil in an effervescent tablet.

Mohrle also provides no direction as to how to include from 50 mg to 200 mg cranberry seed oil in an effervescent tablet --much less how to include such an amount of an oil and still obtain a tablet that disintegrates in water in less than 2.5 minutes. Therefore the person of skill in the art would have no idea as to how to formulate such a tablet and would have no reasonable expectation of successfully achieving a tablet that disintegrates in less than 2.5 minutes. Accordingly, Applicants submit that the rejection of claim 16 under 35 U.S.C. § 103 over Nawar in view of Mohrle is unwarranted, and respectfully request that it be withdrawn.

Claim 31

Claim 31 is directed to an effervescent tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent that includes an acid and a base, binder, and lubricant, the binder being present in the composition in amount of from about 15 % by weight to about 50 % by weight, the tablet being free of picking, capping, die wall etching and lamination.

Neither Nawar nor Mohrle not teach or suggest including from about 15 % by weight to about 50 % by weight binder in an effervescent tablet. Thus, the proposed combination of Nawar and Mohrle lacks a required element of the tablet of claim 31. For this reason alone the rejection of claim 31 under 35 U.S.C. § 103 over Nawar in view of Mohrle is unwarranted and must be withdrawn.

The rejection of claim 31 is further deficient for at least the following additional reasons. The only cranberry extract disclosed in the Nawar and Mohrle is the cranberry seed oil disclosed in Nawar. It is undisputed that Nawar does not teach or suggest how to formulate his cranberry seed oil into an effervescent tablet --let alone an effervescent tablet that includes at least 200 mg cranberry extract and is free of picking, capping, die wall etching and lamination.

Mohrle does not cure the deficiencies of Nawar. Mohrle discloses,

> Granulation sticking to the tablet tools will produce, in the tablet surface, small indentations called picking. Careful observation of the tablet edge can detect early stages of die wall sticking, seen as lines or scratches perpendicular to the tablet face. These are caused by small amounts of granulation adhering to the die wall. If not remedied, this situation will increase in severity and the tablets will not eject freely from the die cavity.
>
> Modifications in the binder and lubrication systems contained in the formulation can solve these problems; but as previously mentioned, the effects of both binders and lubricants are detrimental to tablet disintegration and, in the case of lubricants, the hardness of tablets.

(*Id.*, page 299). Mohrle does not teach or suggest how the skilled artisan would incorporate at least 200 mg of the cranberry seed oil of Nawar into an effervescent tablet so as to achieve a tablet that is free of picking, capping, die wall etching and lamination. Mohrle also does not teach or suggest that at least 200 mg of an oil has been successfully incorporated into an effervescent tablet that is free of picking, capping, die wall etching and lamination. Moreover, Mohrle discloses that oils are used as lubricants. As set forth above, according to Mohrle, lubricants are detrimental to tablet disintegration and tablet hardness. Mohrle further discloses that granulation sticking to the tablet tools will cause picking. Nothing in Mohrle indicates that an effervescent granulation can include at least 200 mg cranberry seed oil, yet not stick to tablet tools or exhibit picking. Therefore, the person of skill in the art would have no reason to believe that an effervescent tablet could be successfully formulated using at least 200 mg of the cranberry seed oil of Nawar. In light of the foregoing, Applicants submit that the rejection of claim 31 under 35 U.S.C. § 103 over Nawar in view of Mohrle is unwarranted and request that it be withdrawn.

Any statements in the December 15th Office action not specifically addressed herein are hereby expressly traversed.

The claims now pending in the application are in condition for allowance and such action is respectfully requested. The Examiner is invited to telephone the undersigned should a teleconference interview facilitate prosecution of this application.

Please charge any additional fees that may be required or credit any overpayment made to Deposit Account No. 501,171.

Respectfully submitted,

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